DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

McKesson Medical Imaging Company
% Mr. Paul Sumner
Director, Regulatory Affairs
McKesson Technologies, Inc.
5995 Windward Parkway
ALPHARETTA GA 30005

May 12, 2015

Re: K142850
Trade/Device Name: McKesson Radiology Mammography Plus™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 15, 2014
Received: December 17, 2014

Dear Mr. Sumner:

This letter corrects our substantially equivalent letter of January 6, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142850

Device Name

McKesson Radiology Mammography Plus™

Indications for Use *(Describe)*

McKesson Radiology Mammography Plus™ ("Mammography Plus"), is an accessory to McKesson Radiology Station™, a component of McKesson Radiology™. McKesson Radiology is medical image and information management software that is intended to receive, transmit, store, archive, retrieve, manage, display, print and process digital medical images, digital medical video and associated patient and medical information. McKesson Radiology™ includes a suite of standalone, web-enabled software components, and is intended for installation and use with off-the-shelf hardware that meets or exceeds minimum specifications.

McKesson Radiology Station™ is the primary software component used for processing and presentation of medical images on display devices with network access to McKesson Radiology. McKesson Radiology Station is intended to process and display lossless and non-lossless compressed medical images provided from DICOM conformant modalities such as X-Ray Radiography (including digital mammography), X-Ray Computed Tomography, Magnetic Resonance Imaging, Ultrasound, and Nuclear Medicine , as well as medical images obtained from other DICOM-compliant modalities.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.

Mammographic images may only be interpreted using cleared monitors intended for mammography display.

McKesson Radiology is indicated for use by qualified healthcare professionals including, but not restricted to, radiologists, non-radiology specialists, physicians and technologists.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
McKesson Medical Imaging Company's
McKesson Radiology Mammography Plus Device

McKesson Medical Imaging Company
130 – 10711 Cambie Road
Richmond, B.C.
Canada, V6X 3G5

510(k) Owner and Contact:	Gilbert Wong Vice President, Regulatory Operations McKesson Medical Imaging Company 130 – 10711 Cambie Road Richmond, BC Canada V6X 3G5 Phone: 604-279-5422 Fax: 604-279-5468 E-mail: Gilbert.Wong@McKesson.com
Date Prepared:	December 15, 2014
Proprietary Name:	McKesson Radiology Mammography Plus™
Common/Usual Name:	PACS
Classification Name:	Picture Archiving Communications System
Classification Regulation:	21 CFR 892.2050
Classification Product Code:	LLZ
Device Class:	Class II
Classification Panel:	Radiology Devices
Predicate Devices:	Hologic, Inc. SecurView DX Diagnostic Workstation (K103385)

Intended Use / Indications for Use

McKesson Radiology Mammography Plus™ ("Mammography Plus"), is an accessory to McKesson Radiology Station™, a component of McKesson Radiology™. McKesson Radiology is medical image and information management software that is intended to receive, transmit, store, archive, retrieve, manage, display, print and process digital medical images, digital medical video and associated patient and medical information. McKesson Radiology™ includes a suite of standalone, web-enabled software components, and is intended for installation and use with off-the-shelf hardware that meets or exceeds minimum specifications.

McKesson Radiology Station is the primary software component used for processing and presentation of medical images on display devices with network access to McKesson Radiology. McKesson Radiology Station is intended to process and display lossless and non-lossless compressed medical images provided from DICOM conformant modalities such as X-Ray Radiography (including digital mammography), X-Ray Computed Tomography, Magnetic Resonance Imaging, Ultrasound, and Nuclear Medicine, as well as medical images obtained from other DICOM-compliant modalities.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.

Mammographic images may only be interpreted using cleared monitors intended for mammography display.

McKesson Radiology is indicated for use by qualified healthcare professionals including, but not restricted to, radiologists, non-radiology specialists, physicians and technologists.

Technological Characteristics

Mammography Plus, an accessory to the McKesson Radiology Station, the radiology viewing component of McKesson Radiology, consists of image display and manipulation tools that help radiologists zoom in onto an image, interpret Computer Aided Detection (CAD) findings, navigate through and visualize digital mammography and Digital Breast Tomosynthesis (DBT) images, compare historically similar images, and configure their reading environment.

Mammography Plus uses the underlying capabilities of McKesson Radiology's diagnostic viewer, McKesson Radiology Station, to integrate specialized functionality into the diagnostic reading workflows. The McKesson Radiology Station viewer interfaces with the McKesson Radiology Platform to access patient and study information.

Performance Data

Verification and validation testing were performed on Mammography Plus to ensure it met all design specifications and documentation was provided as recommended by FDA's guidance for industry and FDA staff entitled "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" which included usability and image quality assessments compared to the predicate(s). Performance testing was conducted to verify compliance with specified design requirements in accordance with ISO 13485:2003, IEC 62304:2006 and ISO 14971:2007/ EN 14971:2012. Additionally, performance testing, specifically bench testing, included testing to conform to consensus standards such as NEMA XR 22-2006, NEMA XR 23-

2006, IEC/ ISO 10918-1:1994, NEMA PS 3.1 - 3.20 (2014) Digital Imaging and Communications in Medicine (DICOM), American Association of Physicists in Medicine (AAPM) TG18 Test Patterns used in conjunction with Assessment of Display Performance for Medical Imaging Systems (AAPM On-line Report No. 03), Society of Motion Picture and Television Engineers (SMPTE) Test Pattern Recommended Practice: Specifications for Medical Diagnostic Imaging Test Pattern for Television Monitors and Hard-Copy Recording Cameras, RP 133-1991 and the Mammography Quality Standards Act (MQSA) (AS AMENDED BY MQSRA of 1998 and 2004).

In all instances, Mammography Plus functioned as intended and the observed results demonstrated substantial equivalence with the predicate devices.

Substantial Equivalence

Mammography Plus is substantially equivalent to the identified predicate devices which include Hologic SecurView DX Diagnostic Workstation (K103385), as well as other similar, if not identical, legally commercially available devices in U.S. Interstate commerce. Specifically, Mammography Plus has the same general intended use and similar indications for use, technological characteristics and principles of operation compared to these previously cleared predicate devices.

As with the predicate device(s), Mammography Plus provides end users with the ability for specialized mammography features such as support for interpretation of Computer Aided Detection Structured Reports (CAD SR), Quadrant Zoom, Historical Similar Images (HSI), Zoom to Fit Anatomy, Zoom to Match Region of Interest (ROI), Unviewed Images Tool, Back-to-Back Placement of Images, and Background Air Suppression. Mammography Plus like the predicate device also provides enhanced features which include processing and displaying Digital Breast Tomosynthesis (DBT) images, and DBT-specific tools such as Display Protocols, Scrolling Mode, Cine Speed, Orientation Indications, Toggling between 2D and 3D Views, and reconstruction of thin-slab visualizations from the DBT slices (also commonly referred to as "slabbing").

Unlike the predicate device(s), however, similar to other mammography image viewing and reporting devices legally marketed in U.S. interstate commerce, including McKesson Radiology (K140909), Mammography Plus also provides the following functionalities:

- The display of BI-RADS® (Breast Imaging-Reporting and Data System) Assessment Categories obtained from prior patient mammography and other breast imaging reports,
- The ability to automatically dim auxiliary monitors, and
- Web-enabled communication functionality for imaging study and patient records access.

None of the additional functionalities raise any new issues of safety and/ or effectiveness.

Thus, Mammography Plus is substantially equivalent to previously-cleared predicate devices.